DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 17, 2015

OK BIOTECH CO., LTD.
JEN KE-MIN
OFFICIAL CORRESPONDENT
NO. 91, SEC. 2, GONGDAO 5TH ROAD
HSINCHU CITY 30070, TAIWAN

Re: K142785
Trade/Device Name: PRODIGY iConnect Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA
Dated: November 25, 2015
Received: December 8, 2015

Dear Jen Ke-min:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142785

Device Name
PRODIGY iConnect Blood Glucose Monitoring System

Indications for Use *(Describe)*

The PRODIGY iConnect Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh. The PRODIGY iConnect Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The PRODIGY iConnect Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The PRODIGY iConnect Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).
PRODIGY No Coding Blood Glucose Test Strips are intended for use with the PRODIGY iConnect blood glucose meter to measure the concentration of blood glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh for self-testing at home. They are for testing outside the body (in vitro diagnostic use only). Do not use them for diagnosis of, or screening for diabetes or for testing on neonates. PRODIGY No Coding Blood Glucose Test Strips are used as an aid to monitor the effectiveness of diabetes control.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510(K) Summary of Safety and Effectiveness *(Per 21 CFR 807.92)*

Type Of 510(K) Submission	Traditional
Basis for the submission	A New Device
Common Name Of The Proposed Device	Blood Glucose Monitoring System
Trade name	*PRODIGY iConnect Blood Glucose Monitoring System*
510(K) Submitter	OK BIOTECH CO., LTD. No. 91, Sec. 2, Gongdao 5th Road, 30070, Hsinchu City, Taiwan Telephone: +886-3-516-0258 Fax:+886-3-516-0028 Email: service@okbiotech.com
Owner Number	9090860
Date prepared	December 16, 2015
Official Correspondent	Dr. JEN, KE-MIN TEL: 886-3-5208829 FAX: 886-3-5209783 Email: ceirs.jen@msa.hinet.net
Preference For Continued Confidentiality (21 CFR 807.95)	510(k) Summary
Classification Regulation	SYSTEM, TEST, BLOOD GLUCOSE, OVER THE COUNTER (21 CFR 862.1345)
Class	II
Panel	Clinical Chemistry
Product Code	NBW, CGA
Predicate Device	*PRODIGY Preferred® Blood Glucose Monitoring System* **(K122338)**

- **Intended Use:**

The PRODIGY iConnect Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh. The PRODIGY iConnect Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The PRODIGY iConnect Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The PRODIGY iConnect Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site

testing should be done only during steady - state times (when glucose is not changing rapidly).

PRODIGY No Coding Blood Glucose Test Strips are intended for use with the PRODIGY iConnect blood glucose meter to measure the concentration of blood glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh for self-testing at home. They are for testing outside the body (in vitro diagnostic use only). Do not use them for diagnosis of, or screening for diabetes or for testing on neonates. PRODIGY No Coding Blood Glucose Test Strips are used as an aid to monitor the effectiveness of diabetes control.

- **Device Description:**

The system is intended for use at home for single patient use. It should not be used for the diagnosis of diabetes or for the testing of newborns. It consists of three main components, i.e., iConnect blood glucose meter, PRODIGY No Coding Blood Glucose Test Strips and 2 levels of Prodigy control solutions (Level 1 & Level 2). The physical components of the meter are Housing, PCBA, LCD and Ear phone jack. The PRODIGY No Coding Blood Glucose Test Strips are not coded. The device has the function of alternative sites testing at Finger, Palm, Forearm, Upper arm, Calf and Thigh

The chemical makeup of the control solutions are as follows:

1. D-Glucose
2.. Antifoaming agent: 0.02%
3. Food Pigment Red No. 6: 0.05%
4. Non-reactive ingredients: 10.5%

The system has the ability of physically connecting to mobile devices for the purpose of obtaining blood glucose determination via a mobile APP.

The PRODIGY iConnect Blood Glucose Monitoring System is marketed as a meter only with a carrying case, battery, Meter User Guide, Quick Reference Guide, Logbook, and Warranty Card. The PRODIGY iConnect Blood Glucose Monitoring System is also marketed as a meter kit with a carrying case, battery, Meter User Guide, Quick Reference Guide, Logbook, Warranty Card, Prodigy Lancing Device, Prodigy Lancets, PRODIGY No Coding Blood Glucose Test Strips, and PRODIGY Control Solution.

If your iConnect blood glucose meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be disinfected prior to use by the second person. Consult your healthcare professional if unusual readings occur.

- **Test Principle**

Blood glucose is measured by an electrical current that is produced when a blood samples mixes with the reagent (special chemicals) of the test strip. The electrical current changes with the amount of glucose in the blood sample. The meter measures the strength of the electrical current, calculates your blood glucose level and then displays your result in either milligrams of glucose per deciliter (mg/dL) or millimoles of glucose per liter (mmol/L)

- **Comparison Table**

Comparison Items	**Subject device**	**Predicate device**	**Safety and effectiveness of subject device compared to the predicate device**
MANUFACTURER	OK Biotech Co., Ltd.	Prodigy Diabetes LLC	OK Biotech is an associate manufacturer with the Prodigy
BRAND NAME	Prodigy	Prodigy	Same brand name
MODEL NO	iConnect	Preferred®	Different models names
Trade Name	PRODIGY iConnect Blood Glucose Monitoring System	Prodigy Preferred® Blood Glucose Monitoring System	Different Trade names
Similarities			
Product Code	NBW, CGA	NBW, CGA	Same product code
510K NO	K142785	K122338	Similar submission

Indications for use	*The PRODIGY iConnect Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh. The PRODIGY iConnect Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The PRODIGY iConnect Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The PRODIGY iConnect Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).* PRODIGY No Coding Blood Glucose Test Strips are intended for use	The Prodigy Preferred Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh. The Prodigy Preferred Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The Prodigy Preferred Blond Glucose Monitoring System is intended **for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home** as an aid to monitor the effectiveness of diabetes control. The Prodigy Preferred Blood Glucose Monitoring System should **not be used for**	Similar indications for use

	with the PRODIGY iConnect blood glucose meter to measure the concentration of blood glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh for self-testing at home. They are for testing outside the body (in vitro diagnostic use only). Do not use them for diagnosis of, or screening for diabetes or for testing on neonates. PRODIGY No Coding Blood Glucose Test Strips are used as an aid to monitor the effectiveness of diabetes control.	**the diagnosis of or screening of diabetes or for neonatal use**. Alternative site testing should be done only during steady -state times (when glucose is not changing rapidly).	
Test Principle	Electrochemical biosensor with carbon electrodes	Electrochemical biosensor with carbon electrodes	Same principle
Enzyme	Glucose oxidase	Glucose oxidase	Same enzyme
Specimen Type	Capillary whole blood from fingertip and alternative sites (palm, forearm, upper-arm, calf and thigh)	Capillary whole blood from fingertip and alternative sites (palm, forearm, upper-arm, calf and thigh)	Same specimen type
Test Strip	PRODIGY® No-Coding Blood Glucose Test Srtips	PRODIGY® No-Coding Test	Same as previous clearance K122338 test

		Strips	strips
Control solution	PRODIGY® Control Solutions (Level 1/ Level 2)	PRODIGY® Control Solutions (Level 1 / Level 2)	Same as previous clearance K122338 control solution
Sample Volume	0.7 µL	0.7 µL	Same volume
Operation Conditions'	10 - 40 °C (39.2 - 104 °F), 10~85% R. H.	10 - 40 °C (39.2 - 104 °F), 10~85% R. H.	Same Operation Conditions'
Strip Storage conditions	4 - 40 °C (39.2 - 104 °F), 10~85% R. H.	4 - 40 °C (39.2 - 104 °F), 10~85% R. H.	Same strip storage conditions
HCT Range	20 ~ 60 %	20 ~ 60 %	Same HCT range
Detecting range	20~600 mg/dL	20~600 mg/dL	Same Detecting range
Power Voltage	One 3V CR2032 battery	One 3V CR2032 battery	Same battery
Differences			
Measuring Time	6 seconds	7 seconds	less measuring time
Meter size	48 mm (L) × 47 mm (W) × 13 mm (H)	71 mm (L) × 60 mm (W) × 19 mm (H)	Smaller meter size
Meter Weight	Approximate 20 g (with battery)	Approximate 45 g (with battery)	less meter weight
Average calculation	Not applicable	7-, 14-, 21- and 28- days	No average calculation
Memory Storage	100 tests	120 tests	Smaller memory storage

- **Substantial Equivalence (SE) Discussion**

A claim of substantial equivalence is made to PRODIGY Preferred® Blood

Glucose Monitoring System (K122338). Both of them have the similar indications for use, the same working principle and technologies, including using the same Prodigy No-Coding test strips and PRODIGY Control Solutions, same enzyme, same specimen type, same sample volume, same operating & strip storage conditions, same HCT range, same detecting range, and same battery.

The major differences for the two devices are **measuring time, meter size, meter weight; average calculation and memory storage**. The smaller meter size and smaller meter weight of the subject device bring more convenient carrying capability to users. Measuring time has only one second difference, and subject device is faster than the predicate device, thus having better performance. Average calculation and memory storage are different. Since the blood glucose measuring data vary much because of the user's diet status, the meaning of average calculation is not significant. The memory storage is 100-set data for the subject device and 120 sets for the predicate device. The meaning of the memory storage is for user's recalling reference and 20 sets difference is not significant for recall, thus not raising any safety and effectiveness concerns.

Besides, the subject device and predicate device have the same intended uses in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. Thus the differences are due to the feature design aspects, not related to the safety or effectiveness aspects.

- **Summary of the Non-Clinical Performance Characteristics**

The following non-clinical testing were conducted on the *PRODIGY iConnect Blood Glucose Monitoring System* to show substantial equivalence to the predicate device:

- Software verification and validation testing (IEC 62304:2006, FDA Guidance, 5/2005)
- Electromagnetic Compatibility Study (IEC 60601-1-2:2007: Electromagnetic Compatibility, IEC 61326-1:2012, IEC 61326-2-6:2005, Emission: CISPR 11:2009 +A1:2010, Class B, Immunity: IEC 61000-4-2:2008, IEC 61000-4-3:2010, IEC 61000-4-8:2009
- Electrical Safety testing (IEC 60601-1: 2005, IEC 61010-1:2010, IEC 61010-2-101:2002, FCC 47 CFR Part 15 Subpart B/Oct. 2013 and CISPR 22/1997 (Class B Limit)
- Robustness Evaluation (FDA Guidance, Jan/2014)
- Precision Evaluation (FDA Guidance 02/28/1997, ISO 15197:2013, NCCLS EP5-A2)
- Linearity Evaluation (NCCLS/CLSI, EP6-A, FDA Guidance 02/28/1997, ISO 15197:2013)
- System Accuracy Evaluation (ISO 15197:2013, FDA Guidance 02/28/1997)
- Hematocrit Evaluation (FDA Guidance 02/28/1997, ISO 15197:2013,)

- Interference Study (FDA Guidance 02/28/1997, ISO 15197:2013, CLSI EP7-A2)
- Operation Condition Study (ISO 15197:2013, EN 13640)
- Sample Volume Study (ISO 15197:2013)
- Virucide Evaluation for Case & Lens materials (CLSI EP17-A)
- Altitude Study (FDA Guidance 02/28/1997, ISO 15197:2013)
- Mechanical Resistance Study (ISO 15197:2013, IEC 60068-2-64:1993, IEC 61010-1:2010)
- Shelf-Life Study (ISO 15197:2013)

Testing demonstrated the *PRODIGY iConnect Blood Glucose Monitoring System* meets all relevant standards requirements. Internal verification and validation testing confirms that the product specifications are met which are equivalent in design and technological characteristics to the predicate device. Testing of the *PRODIGY iConnect Blood Glucose Monitoring System* supports the claims of substantial equivalence to the predicate device.

Software: All software documentation was prepared and submitted for the device in accordance with FDA guidance documents. The software was tested against the established Software Design Specifications for each of the test plans to assure the device performs as intended. The Device Hazard Analysis was completed, and risk control implemented to mitigate identified hazards. The testing results support that all the software specifications have met the acceptance criteria of each module and interaction of processes. *The PRODIGY iConnect Blood Glucose Meter and APP* software verification and validation with HTC and Apple platforms demonstrated safety and effectiveness of the *PRODIGY iConnect Blood Glucose Monitoring System*.

Electrical safety: The PRODIGY iConnect Blood Glucose Monitoring System complies with the applicable voluntary standards for the Electrical Safety. The device with Apple or HTC platform passed all the electrical safety testing according to national & international standards including IEC 60601-1: 2005, IEC 61010-1:2010, IEC 61010-2-101:2002, FCC 47 CFR Part 15 Subpart B/Oct. 2013 and CISPR 22/1997 (Class B Limit).

Electromagnetic Compatibility The PRODIGY iConnect Blood Glucose Monitoring System with Apple or HTC platform has been tested and successfully met all of the relevant sections (Radiated Emissions, Electrostatic Discharge Immunity Test, Radiated Radio-Frequency Electromagnetic Immunity, and Power Frequency Magnetic Field Immunity Test to complies to all standards including IEC 60601-1-2:2007: Electromagnetic Compatibility, IEC 61326-1:2012, IEC 61326-2-6:2005, Emission: CISPR 11:2009 +A1:2010, Class B, Immunity: IEC 61000-4-2:2008, IEC 61000-4-3:2010, IEC 61000-4-8:2009.

Robustness Study: The PRODIGY iConnect Blood Glucose Monitoring System is intended for single-patient use. According to the study results with the use of PDI SUPER SANI-CLOTH germicidal disposable wipes (EPA Reg. No. 9480-4), the appearance, structure and function of the meters and the lancing device were quite regular after cleaning and disinfection cycles 3,650 times. Also, based on the accuracy test, all the individual bias of the test results compared with YSI mean were less than 10 mg/dL at glucose concentrations < 75 mg/dL and less than ± 10 % at glucose concentrations ≥ 75 mg/dL. The test results met acceptance criteria. The subject device passes the Robustness Study.

Precision Evaluation: The PRODIGY iConnect Blood Glucose Monitoring System was evaluated in accordance with FDA Guidance 02/28/1997, NCCLS EP5-A User Evaluation of Precision Performance of Clinical Chemistry Devices and ISO 15197:2013. The subject device within-run and between-run tests over the blood glucose concentration range of 20-600 mg/dL and Control Levels 1 and 2 showed the pooled Standard Deviation were less than 5.0 mg/dL at glucose concentration < 100 mg/dL, and pooled Coefficient of Variation were less than 5.0% at glucose concentration ≥ 100 mg/dL for within runs and between runs compared to the YSI reference standards over the course of ten days. The test results met the acceptance criteria. The subject device passes the Precision Evaluation.

Linearity Evaluation: The PRODIGY iConnect Blood Glucose Monitoring System was tested to determine the linearity in accordance with CLSI document EP6-A, "Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach" and ISO 15197: 2003. The PRODIGY iConnect Blood Glucose Monitoring System was shown to demonstrate high linearity over the range 10.46 mg/dL to 672.9 mg/dL. The claimed blood glucose measuring range is 20 to 600 mg/dL, same as the predicate device. Linear regression showed the correlation coefficient is greater than 0.95, as shown in the following Table. That is, our test results were highly correlated with YSI 2300. The linearity of our measurement is acceptable between 20 to 600 mg/dL. 100 % of the bias of individual glucose results fallen within ±10 %. The test results met the acceptance criteria. The subject device passes the Linearity Evaluation.

Table: The separate regression analysis for each lot of test strips

Test Strip Lot	Slope	y-intercept	R^2
Lot I	1.0001	-0.8111	0.9997

Lot II	1.0036	-3.0874	0.9998
Lot III	1.0026	-2.1376	0.9999

System Accuracy Evaluation: The PRODIGY iConnect Blood Glucose Monitoring System was evaluated for system accuracy using YSI as the reference standard. According to the internal test results, ≥96.9% of tests for which the differences fell within ±15 mg/dL for glucose concentration <75 mg/dL, and 100% within 20% at glucose concentration ≥75 mg/dL. A study evaluating glucose values from fingertip, palm, forearm, upper arm, calf, and thigh capillary blood samples obtained by 350 lay persons showed the following results. The test results of PRODIGY iConnect Blood Glucose Monitoring System met the acceptance criteria. The subject device passes the System Accuracy Evaluation.

For glucose concentrations < 75 mg/dL

Site	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Finger	**18/32 (56.3%)**	**31/32 (96.9%)**	**32/32 (100%)**
Palm	**16/32 (50.0%)**	**30/32 (93.8%)**	**30/32 (100%)**
Forearm	**21/32 (65.6%)**	**31/32 (96.9%)**	**31/32 (100%)**
Upper arm	**24/32 (75.0%)**	**32/32 (100%)**	**32/32 (100%)**
Calf	**18/32 (56.3%)**	**31/32 (96.9%)**	**31/32 (100%)**
Thigh	**15/32 (46.9%)**	**31/32 (96.9%)**	**31/32 (100%)**

For glucose concentrations ≥ 75 mg/dL

Site	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20%
Finger	**150/318 (47.2%)**	**251/318 (78.9%)**	**310/318 (97.5%)**	**318/318 (100%)**
Palm	**158/318 (49.7%)**	**262/318 (82.4%)**	**309/318 (97.2%)**	**318/318 (100%)**
Forearm	**160/318 (50.3%)**	**256/318 (80.5%)**	**311/318 (97.8%)**	**318/318 (100%)**
Upper arm	**137/318 (43.1%)**	**247/318 (77.7%)**	**302/318 (95.0%)**	**318/318 (100%)**
Calf	**159/318 (50.0%)**	**257/318 (80.8%)**	**312/318 (98.1%)**	**318/318 (100%)**
Thigh	**131/318 (41.2%)**	**241/318 (75.8%)**	**305/318 (95.9%)**	**318/318 (100%)**

Hematocrit Evaluation: The effect of varying hematocrit (HCT) levels on the performance of the PRODIGY iConnect Blood Glucose Monitoring System was evaluated over an HCT range of 20-60%. All of the individual difference of the blood

glucose measurements compared with individual YSI mean fall within ±15% from HCT 20% to 60%. Also, % bias difference on mean value of the blood glucose measurements fall within 8% compared with the mean of blood glucose measurements in HCT 40% from HCT 20% to 60%. The test results met the acceptance criteria. In summary, the HCT ranges from 20% to 60% were available for PRODIGY iConnect Blood Glucose Monitoring System.

Interference Study: The interference study was completed per CLSI EP7-A2: Interference Testing in Clinical Chemistry; Approved Guideline-Second Edition. Interference studies were performed on the PRODIGY iConnect Blood Glucose Monitoring System and PRODIGY No-Coding Blood Glucose Test Strips. Seven endogenous and nineteen exogenous interfering substances were evaluated by spiking venous blood to three levels of glucose concentrations (60, 120, 250 mg/dL). The glucose samples were then spiked with the potentially interfering compounds. Ten meters and three lots of test strips were used for this study. Bias was calculated as the mean percent difference in glucose reading between the test and control concentration groups. The bias of mean test results within the range listed above were ≤ 10% compared with the YSI mean measurements. Based on the results, the concentration limits of all the interfering substances were higher than therapeutic or physiological levels. That is, no obvious interference was observed in the interfering substance at neither therapeutic nor physiological levels at three blood glucose levels. A summary of the maximum concentrations of the potential interfering substances tested is summarized in the table below:

Chemical	**Max Concentration**
1. Acetaminophen	≤ 8.0 mg/dL
2. Ascorbic acid	≤ 5.0 mg/dL
3. Aspirin	≤ 60 mg/dL
4. Bilirubin (unconjugated)	≤ 90 mg/dL
5. Cholesterol	≤ 500 mg/dL
6. Creatinine	≤ 5.0 mg/dL
7. Dopamine	≤ 2.0 mg/dL
8. EDTA	≤360 mg/dL
9. Galactose	≤ 900 mg/dL
10. Gentisic acid	≤ 5.0 mg/dL
11. Glutathione	≤53 mg/dL
12. Haemoglobin	≤500 mg/dL
13. Heparin	≤8000 U/dL
14. Hydroxyurea	≤ 3.0 mg/dL
15.Ibuprofen	≤50 mg/dL
16. Icodextrin	≤13 mg/dL
17. L-dopa	≤ 10 mg/dL
18. Maltose	≤ 900 mg/dL
19. Methyldopa	≤ 3.0 mg/dL
20. Pralidoxime Iodide	≤25 mg/dL
21. Salicylate	≤60 mg/dL

22. Tolazamide	≤100 mg/dL
23. Tolbutamide	≤ 400 mg/dL
24. Triglyceride	≤ 2000 mg/dL
25. Uric acid	≤ 8.0 mg/dL
26. Xylose	≤100 mg

Operation Condition Study: This study confirmed the operation conditions of the PRODIGY iConnect Blood Glucose Monitoring System for the temperature range of 4 - 40 ^{o}C (39.2 - 104 ^{o}F), and the relative humidity range of 10~85%.

Sample Volume Study: Based on the data evaluation, the test values of volumes between 0.7 and 1.5 μL were fall within acceptable criteria. In order to obtain more accurate results, testing blood glucose value with the PRODIGY iConnect Blood Glucose Monitoring System is required at least 0.7 μL of blood sample.

Virucide Evaluation for Case & Lens materials: The study indicated that PDI SUPER SANI-CLOTH germicidal disposable wipes (EPA Reg. No. 9480-4) within 2 minutes contact time can completely inactivate the Hepatitis B Virus at undiluted (HBsAg: 7857.9 IU/mL), 10X, 100X and 1000X virus dilution on the Case & Lens coupons.

Altitude Study: The study shows the individual results fall within ± 10 % at the altitude below 11,161 feet (3,402 meters). The results met the acceptance criteria. So it shows no significant effects on PRODIGY iConnect Blood Glucose Monitoring System at the altitudes below 11,161 feet (3,402 meters).

Mechanical Resistance Study: The PRODIGY iConnect Blood Glucose Monitoring System was examined to test the operational limits of the system and to validate the insensitivity of the system to performance variation under stress conditions. Accordingly, the following tests were carried out:

1) Vibration test: Ten iConnect meters were subjected respectively to vibration tester for 30 min for X axis, 30 min for Y axis and 30 min for Z axis, then doing the blood glucose measurement with 3 lots of test strips.
2) Drop test: Ten iConnect meters are released respectively from 1 meter high above a horizontal hardwood, then doing the blood glucose measurement with 3 lots of test strips.

All studies showed the meters could stand the vibration and drop testing required in ISO 15197:2013, IEC 60068-2-64:1993 and IEC 61010-1: 2010.

Shelf-Life Study: According to the test result, all the data met the acceptance criteria. That is, the unused test strips were stable for 25 months and 96 days for opened vials. We can claim the shelf-life of PRODIGY Blood Glucose Test Strip is 24 months for unopened strips vials and 90 days for opened strips vials.

Synopsis of Test Methods and Results

Pre-clinical and clinical data are employed upon submission of this 510(K) premarket notification according to the *Guidance Document for In Vitro Diagnostic Test System;*

Guidance for Industry and FDA document provided by CDRH/ FDA.

- **Conclusion**

The conclusions drawn from the non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device identified in the submission. Thus the subject device is substantially equivalent to the predicate devices.